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10/743,281	12/22/2003	Anita Melikian	10709/63	4482
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BRINKS HOFER GILSON & LIONE			EXAMINER	
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			ART UNIT	PAPER NUMBER
			1616	
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			09/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/743,281

Applicant(s)

MELIKIAN ET AL.

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,7-9,14-18,23,28 and 34-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,10,12,13,19-22,24-27,29-33 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2,4,7-9,14-18,23,28 and 34-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Non-Final Office Action

Claims 1-38 are pending. No claim is allowed at this time. Claims 1, 3, 5, 6, 10, 12, 19-22, 24-27, 29-33 are examined; others are withdrawn as non-elected invention.

Summary of this Office Action dated 8/25/2007

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. Election/Restriction
4. Double Patenting Rejections
5. 35 USC 103 Rejection
5. Communication

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See *Dayco Products Inc. v. Total Containment Inc.*, 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 3, 5, 6, 10, 12, 19-22, 24-27, 29-33, drawn to compounds of formula I when Z is NR₁R₂, R₁ and R₂ forms a five member ring containing one nitrogen and is the only heterocyclic group present, (elected species is compound 57), classified in class 548 subclass 574, 491, 561 and (various).
 - II. Claims 1-38, drawn to compounds of formula I when Z is NR₁R₂, R₁ and R₂ forms a six member ring containing one nitrogen and is the only heterocyclic group present, classified in class 546, subclass 184, 186, 337, 343, 491 and 561.
 - III. Claims 1-38, drawn to compounds of formula I when Z is NR₁R₂, R₁ and R₂ forms a six member ring containing one nitrogen and one oxygen (morpholine) and is the only heterocyclic group present, classified in class 544, subclass 106, 107.
 - IV. Claims 1-38, drawn to compounds of formula I when Z is NR₁R₂, R₁ and R₂ forms a six member ring containing one nitrogen and one sulfur (thiamorpholine) and is the only heterocyclic group present, classified in class 544 subclass 3 and (various).
 - V. Claims 1-38, drawn to compounds of formula I when Z is NR₁R₂, R₁ and R₂ forms a six member ring containing two nitrogens (1, 4 diazine) and is the only heterocyclic group present, classified in class 544, subclass 120, 121, 122 and (various).

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- VI. Claims 1, 3, 5, 6, 10, 12, 19-22, 24-27, 29-33, drawn to compounds of formula I when Z is NR₁R₂, R₁ and R₂ forms a 5 member ring containing two nitrogen and is the only heterocyclic group present, classified in class 548 subclass 356.1 and (various).
- VII. Claims 1-34, drawn to compounds of formula I when Z is -NR₁R₂, R₁ and R₂ are substituted or unsubstituted alkyl and hydrogen, (no heterocyclic group is present in the compound, classified in class 564, subclass (various).
- VIII. Claims 1-34, drawn to compounds of formula I when Z is CHR₁R₂ and no heterocyclic group is present, classified in class 560, 562, subclass (various).
- IX. Claims 35 and 36, drawn to a method of inhibiting the binding of chemokines 1-TAC and/or SDF-1 to a CCXCKR2 receptor, classified in class 514, subclass (various).
- X. Claims 37 and 38 are drawn to a method of treating cancer by the compounds of claim 1, classified in class 514, subclass (various).
- XI. Claims 1-33 drawn to the invention not covered by the cited groups.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of groups and group are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP

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§ 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product.

3. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have a materially different design, mode of operation, function, or effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

MPEP--802 Bases for Practice in Statute and Rules

The basis for restriction and double patenting practices is found in the following statute and rules:

35 U.S.C. 121. Divisional applications.

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.

37 CFR 1.142. Requirement for restriction.

(a) If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action.

(b) Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.

7. Claims 1-13 and 20-38 are generic to the following disclosed patentably distinct species: The species are independent or distinct because they belong to various different classes of compounds, which are chemically different. It would be a burden on the examiner to search all the invention as claimed. The invention is drawn to various independent and distinct inventions. Each of them are patentable distinct. For example compounds containing morpholine is not the

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same as containing a pyrrole. Similarly compounds containing pyrimidine is not the same as compounds containing morpholine and so is different from imidazole containing compounds. Compounds containing pyridines are different from the compounds containing morpholine or pyrimidine. No one of the cited compounds are similar.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon; including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. A telephone call was made to Attorney K. Shannon Mrksich on 8/31/2007 to discuss the issues on the restriction requirement as in remarks. Attorney was not available at that time. A message was left. Examiner has revised restriction requirement in view of the arguments. In order to advance the prosecution examiner has search group I, which includes elected species of compound 57, which is used for the search purposes of the invention of group I.

10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Eligible for Rejoinder of method claims

In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim. A withdrawn claim that does not require all the limitations of an allowable claim will not be rejoined. Furthermore, where restriction was required between a product and a process of making and/or using the product, and the product invention was elected and subsequently found allowable, all claims to a nonelected process invention must depend from or otherwise require all the limitations of an allowable claim

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for the claims directed to that process invention to be eligible for rejoinder. See MPEP § 821.04(b).

Until elected product claim is found allowable, an otherwise proper restriction requirement between products claims and process claims may be maintained. Withdrawn process claim that are not commensurate in scope with an allowed product will not be rejoined. See “Guidance on Treatment of Product and process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103 (b),” 1184 O.G. 86 (March 26, 1996).

In order to retain the right to rejoinder, applicant is advised that the claims to the nonelected invention(s) should be amended during prosecution to require the limitations of the elected invention. Failure to do so may result in a loss of the right to rejoinder. Rejoined claims must be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112.

See also MPEP § 804.01.

Double Patenting Rejection

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-38 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No.

11/202961. Although the conflicting claims are not identical, they are not patentably distinct from each other because structurally similar compounds have been claimed in copending application. It would have been obvious to one skilled in the art to prepare the compounds as claimed in present application containing a five member ring containing one nitrogen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1-38 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No.

11/478,456. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of copending application are drawn to compounds containing a 5-membered ring containing one nitrogen as Z group (which is the elected invention). Same invention has been claimed in present application. Applicant's elected invention is the same as claimed subject matter of copending application.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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18. Claims 1, 3, 5, 6, 10, 12, 13, 19-22, 24-27, 29-33 and 38 rejected under 35 U.S.C. 103(a) as being unpatentable over ERIKSSON et al. (WO 01/98272). The reference generically teaches structurally similar compounds, which embraces applicant's claimed invention. See the entire document especially formula (I) on page 2, compounds on pages 11-15, examples and claims.

Instant claims differ from the reference in that they are of different generic scope. Claimed invention is drawn to the compounds of formula (I) when Z represents a 5-membered heterocyclic ring containing one nitrogen. Similar compounds are taught by the prior art. It had been decided by Courts that the indiscriminate selection of "some" from among "many" is considered prima facie obvious. In re Lemin, 141 USPQ 814 (1964); National Distillers and Chem. Corp. V. Brenner, 156 USPQ 163.

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare compounds embraced by the genus of the above cited references with the expectation of obtaining additional beneficial compounds. The instant claimed compounds would have been suggested to one skilled in the art.

One having ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. V. Biocraft Laboratories, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

No criticality of invention and/or unexpected was noted.

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In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have obvious to one skilled in the art.

Response to Remarks

- Election of species of compound 57 is acknowledged. Claims read on the elected species are 1, 3, 5, 6, 10, 12, 13, 19-22, 24-27, 29-33 and 38. Arguments and traversal of election of species were fully considered but are not found persuasive. Examiner disagree that core structure exists so there is no need for any restriction requirement and claim 1 is allowable. Furthermore, applicant argues "claim 1 has several points of variability, some of which are defined to include various heterocycles". There is no core as claims are drawn to various substituents, which are divergent subject matter. Each is drawn to a different patent. See the reasons in detail in the restriction section of this action.
- Examiner disagrees because each heterocyclic group is drawn to a different compound or class of compounds, which are patentability distinct. A reference used to rejection for example a compound containing a piperidine cannot be used to reject compound containing a morpholine.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D
PRIMARY EXAMINER